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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,372	06/27/2003	Sung-Soo Park	75766-NEW	8012

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,372	PARK, SUNG-SOO	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/27/06</u> <u>9/2/03</u> : <u>2/28/06</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Susan Hanley is now the examiner for this application.

Election/Restrictions

Applicant's election of Group I in the reply filed on 5/17/06 is acknowledged. Applicant's election with traverse of Group I, claims 1-14, in the reply filed on 5/17/06 is acknowledged. The traversal is on the ground(s) that the unelected methods can not be practiced without the teachings of the present disclosure. Applicant asserts that the method is unusable outside of the disclosed system and that the system can not be used with a materially different process and still maintain the organ level functionality. Applicant concludes that the method and the system are essential to one another. This is not found persuasive because the system is very similar to that disclosed by US 5,773,285, which is used for culturing hepatocytes. for example, US 5,773,285 (cited in the IDS filed on 9/2/03). Clearly, the apparatus, as claimed, has uses beyond detoxification of blood or plasma. Hence, Applicant's arguments are found non-persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/17/06.

Claims 1-14 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4, 5, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5, 11 and 12 recite the limitation "gas-to-plasma." There is insufficient antecedent basis for this limitation in claim 1 (for claims 4 and 5) or claims 8 or 10 (for claims 11 and 12). Claims 1 and 8 recite that a gas and plasma enter the apparatus but there is not limitation that indicates that the gas and the plasma are intimately contacted such that there is an "exposure time".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Park (US 5,976,870; cited in the IDS filed 9/2/03).

Park discloses an artificial liver comprising a static culture apparatus for treating hepatic failure. The device comprises a separator for the separating the patient's blood into plasma and blood cells, a liver culture device for detoxifying the plasma and a means for circulating the patient's blood to the plasma separator and means for recirculating the detoxified plasma and blood back to the patient. The separated plasma is sent to a plasma reservoir (col. 3, lines 35-38). The device comprises a sealable chamber with a medium inlet and gas valve (col. 5, lines 40-53). The liver slices are positioned between mesh screens that are approximately horizontal to one another (col. 3, lines 1-6 and Fig. 2). The mesh screens allows the medium to contact the liver slices. The chamber has a reservoir for the medium (col. 3, lines 61-65) and the gas can be a mixture of oxygen/carbon dioxide (see Figure 2 and col. 2, lines 45-68),

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as in instant claims 3 and 10. This disclosure meets, in part, the limitations of instant claim 1. The remaining limitations of instant claim 1 regarding medium exposure at regular intervals is disclosed by Park at col. 3, lines 18-25. Park teaches a means to introduce oxygen and carbon dioxide to the chamber at the top of the chamber (col.4, lines 22-34). Park discloses gas-to-plasma exposure times of about 1:2 to about 1:4 and 1:2.5 to 1:3.5, as in instant claims 4, 5, 11 and 12 (col. 3, lines 25-30). This disclosure meets the limitations of "about 1:3, as in instant claim 9, because 1:2.5 and 1:3.5 are about 1:3. The instant limitation of an immunological filter is met by the Park patent in col. 4, lines 8-20. The detoxified plasma stream is collected at the bottom of the chamber and recirculated via a second plasma reservoir (col. 3, lines 62-65), as in instant claims 2 and 9.

This disclosure meets the limitation wherein the chamber is thermoregulated. "Thermoregulated" is interpreted to mean that the temperature in the chamber varies due to some manipulation. The universal gas law, $PV=nRT$, applies to the sealed chamber in that the volume of the chamber (V), the number of moles of gas in the chamber (n) and the universal gas constant R are constant. Thus, the pressure (P) and temperature (T) are directly proportional. The pressure in the chamber will change with the medium is pumped in. Thus, the temperature will vary, or be regulated by, its response to the pressure changes.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 3, 4, 8, 10, 11 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,976,870. Although the conflicting claims are not identical, they are not patentably distinct. Instant claim 1 is drawn to a system comprising a liver-slice apparatus having certain physical features that are discussed supra. In '870, the features recited in the dependent claims 2 and 3 are clearly disclosed species in the broad claim which suggest the same. Clearly, species within a generic disclosure are obvious.

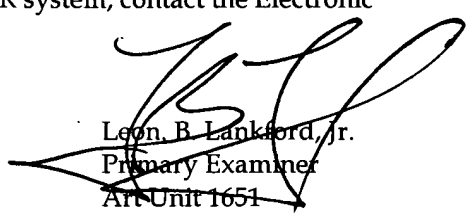
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651